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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,824	05/14/2001	Kristin J. Godbey	56466USA.002	9149

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,824	GODBEY ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicants': (a) amendments to the claims and remarks (both filed on 9 September 2006) and (b) IDS (filed on 6 November 2006).

2. The amendments to the claims, filed on 9 September 2006, have been entered.

3. Currently pending claims 1-39 remain rejected under 35 U.S.C. 103(a).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sieverding (U.S. Patent No. 4,750,482) in view of Katz, et. al. (U.S. Patent No. 5,028,435).

Sieverding teaches (*see* fig. 2) a hydrophilic, elastomeric, pressure-sensitive adhesive which may be used as a coating on a supportive web-like substrate for delivering an active agent, as well as a cosmetic face mask (*see* col. 17, lines 29-33; col. 18, lines 28-57). Examples of the pharmacologically active agents include analgesics, hormones and antirheumatics.

Sieverding discloses that the adhesive may be used as a carrier for a depilatory agent (*see* col. 18, lines 54-57) and may contain skin conditioners, perfumes, acne medication, antiperspirants, sunscreens, sun tanning materials and humectants.

Sieverding teaches polymers consisting of polyvinyl alcohol, monomers, polyhydric alcohols such as glycerin and propylene glycol (see col. 9, lines 31-68; col. 10-14).

The Sieverding reference differs from the instant case only in that it does not teach use of a protein and a carbohydrate.

Katz, et. al. teach use of a protein and a carbohydrate in a transdermal system.

Katz, et. al disclose a transdermal delivery system comprising a backing having a matrix layer which incorporates a drug and a percutaneous enhancer for the drug. At least one of the drug and enhancer is contained within a plurality of polymeric particles dispersed throughout the matrix layer (*see* col. 3, lines 58-62). The particles may be formed using natural polymers such as arabinogalactan and gelatin (see col. 7, lines 28-32).

Katz, et. al. explain that polymers such as arabinogalactan and gelatin are useful because they contribute to the stability of the transdermal drug delivery device, as well as to a long shelf life for the device (*see* col. 7, lines 14-19).

Thus, it would have been obvious for one of ordinary skill in the art at the time of the invention to add a protein, such as collagen, and a carbohydrate, such as arabinogalactan to a transdermal delivery device, as taught by Sieverding in view of

Katz, et. al. Motivation to do so, as explained above, would come from increased stability and longer self life of the device.

* * * * *

Response to Arguments

Applicants' arguments filed on 9 September 2006 have been fully considered but they are not persuasive.

1. Applicants argue that the Sieverding reference, "...fails to teach or suggest a water-soluble or water-dispersible adhesive." *See* Remarks, page 8, third paragraph.

Examiner respectfully disagrees. According to Merriam-Webster dictionary (online edition at www.m-w.com, last checked on 21 November 2006), the word "disperse" is defined, inter-alia, "to cause to become spread widely" or "to distribute...more or less evenly throughout a medium."

The Sieverding reference teaches a hydrophilic, elastomeric, pressure-sensitive material (*see* abstract). An inherent feature of hydrophilic, elastomeric, pressure-sensitive materials is that they expand (spread widely) and absorb water in a more or less even distribution.

The claims, as currently constructed, recite the phrase "water-dispersible." This hyphenated compound adjective suggests expansion of and distribution of water within the noun being described.

Thus, the Sieverding reference reads upon the instant claims as currently constructed.

It should be noted that the term "dispersible" is not independently defined in the instant specification.

2. Applicants recite the following hypothetical: "...[O]ne skilled in the art could treat the surface of a piece of plastic to make it hydrophilic by the standard definition, but that does not make the piece of plastic "water-dispersible". *See* Remarks, page 8, third paragraph.

Examiner respectfully submits that this hypothetical is not analogous to the instant case because the physical properties of plastic are very different from the materials disclosed both in the prior art references as well as in the instant application.

3. Applicants argue that, "...any interpretation of Sieverding to equate "hydrophilic" with "water-dispersible" ignores the teachings of Sieverding in both its description and its applications." Further, applicants direct examiner to the language recited in col. 5, lines 57-58 and col. 6, line 14 of the Sieverding reference, arguing that, "...Seiverding's adhesive is structure [sic] that will absorb fluid and not break apart even if squeezed". *See* Remarks, page 8, paragraphs 3 and 4 (continuing to the top of page 9).

Examiner respectfully submits that equating "hydrophilic" with "water-dispersible" fully comports with the teachings of the Sieverding reference in both its description and its applications. For instance, the absorption of fluid by the Sieverding adhesive suggests expansion of the adhesive, as well as even distribution of water within the adhesive. Thus, the fact that Sieverding's adhesive is hydrophilic means that it is water-dispersible, as the phrase is commonly defined (*see* above).

It should be noted that the fact that Sieverding's adhesive does not break apart is not relevant, since the instant claims recite a "water-dispersible" material, not a material that will "break-apart" in water.

4. Applicants argue that, "...the (Sieverding) adhesive is clearly a crosslinked three dimensional polymer network...and NOT an adhesive dispersible in water." *See* Remarks, page 9, first full-paragraph.

Examiner respects that the crosslinking of a material and the dispersion of that material are not mutually exclusive. Thus, the material disclosed by Sieverding is both crosslinked and dispersible in water, as explained above.

5. Applicants direct examiner to col. 8, lines 37-39 and col. 17, lines 47-48 of the Sieverding reference, explaining that the cited language discloses a "bacterial barrier." Applicants further argue that, "[a] bacterial barrier should remain intact to function as a barrier. This would NOT be possible with an adhesive system that is dissolved or dispersed in water." *See* Remarks, page 9, second full-paragraph.

The following is a direct quote from col. 8, lines 37-39 of the Sieverding reference: "My adhesive will filter out microorganism contaminants by presenting a tortuous path for the influx of bacteria."

The following is a direct quote from col. 17, lines 47-48 of the Sieverding reference: "My adhesive will significantly reduce bacterial influx by filtering bacteria out."

Examiner respectfully submits that, contrary to applicants' assertion, the language recited above does not disclose a "bacterial barrier." Rather, the reference discloses a filtering mechanism by virtue of a "tortuous path for the influx of bacteria."

This language does not suggest an intact barrier; rather, it suggests a dispersion, which in turn creates a tortuous path – difficult for bacteria to traverse.

6. Applicants argue that, "...Sieverding fails to teach a a [sic] water-soluble or water-dispersible carrier." *See* Remarks, page 9, third full-paragraph.

Examiner respectfully submits that the fabric layer disclosed by Sieverding is a functional equivalent of the instant water-dispersible carrier (*see* figure 1; col. 9, lines 1-19) since the fabric will inherently expand when absorbing water.

7. Applicants argue that, "...Sieverding fails to disclose any construction of a device in which a support layer is attached to a carrier on the surface opposite the adhesive layer." *See* Remarks, page 9, fourth full-paragraph.

Examiner respectfully submits that the construction described in figure 1 and col. 9, lines 9-18 is a support layer attached to a carrier on the surface opposite the adhesive layer.

8. Applicants argue that, "Katz...fails to cure the deficiencies of Sieverding because Katz fails to teach or disclose a cold-water soluble/water dispersible carrier layer, cold-water soluble/water dispersible adhesive layer, and a support layer." *See* Remarks, page 9, fifth paragraph.

Examiner respectfully submits that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the

references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Katz was used here as a secondary reference, merely to show that use proteins and carbohydrates in a transdermal system is known in the art. It was not used for the teaching of a cold-water soluble/water dispersible carrier layer, cold-water soluble/water dispersible adhesive layer, and a support layer; the primary reference, Sieverding was used for that purpose.

☆

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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